

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	Case No. 4:20-CR-00098 HEA-JMB
)	
v.)	
)	
ASIM ALI, <i>et al.</i> ,)	
)	
Defendants.)	

**GOVERNMENT’S RESPONSE IN OPPOSITION TO
STANLEY LIBRACH’S MOTION TO QUASH SUBPOENA DUCES
TECUM AND TO REVOKE OR AMEND THE COURT’S MARCH 31, 2022 ORDER**

Comes now the United States of America, by and through its attorneys, Sayler A. Fleming, United States Attorney for the Eastern District of Missouri, and Amy E. Sestric and Dorothy L. McMurtry, Assistant United States Attorneys for said District, and states the following in opposition to the “Motion to Quash Subpoena Duces Tecum and To Revoke or Amend the Court’s March 31, 2022 Order.” Doc. 688 (“Motion”). For the reasons discussed below, the Government urges the Court to deny the Motion.

I. INTRODUCTION

On April 27, 2022, a federal grand jury charged Stanley L. Librach, M.D. (“Librach”) in 42 counts of a 44-count superseding indictment¹ with conspiracy, illegal distribution of controlled

¹ Count 1 charges Librach, Asim M. Ali (“Ali”), and Sally Hydar (“Hydar”) with conspiring to commit offenses against the United States from in or about 2013 to at least in or about 2021, in violation of 18 U.S.C. § 371. Counts 2 through 10 charge Librach and Ali with distributing Schedule II controlled substances outside the scope of professional practice and not for a legitimate medical purpose from in or about 2016 to in or about 2018, in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2. Counts 11 through 20 charge Librach and Ali with obtaining and assisting others to obtain controlled substances by fraud, deception, and subterfuge from in or about 2016 to in or about 2018, in violation of 21 U.S.C. § 843(a)(3) and 18 U.S.C. § 2. Counts 21 through 26 charge Ali and Counts 27 through 45 charge Librach and Hydar with soliciting, paying, or

substance medication, obtaining and assisting others to obtain controlled substances by fraud and deceit, and soliciting and receiving illegal kickbacks. Doc. 630.

On May 27, 2022, the United States Department of Justice (“DOJ”), acting through the United States Attorney’s Office for the Eastern District of Missouri (“USAO”), issued an administrative subpoena (“Subpoena”) pursuant to 18 U.S.C. § 3486 to the “Custodian of Records for Stanley Librach, M.D. D.D.S., LLC” (the “Suboxone Clinic”), a narcotic abuse treatment clinic owned and operated by Librach. The Subpoena sought medical records and billing documents for five patients of the Suboxone Clinic for the period from January 1, 2013, to the present.

The Public Health Service Act (“PHSA”), 42 U.S.C. § 290dd-2, affords special protections to patient records maintained by certain substance abuse treatment facilities, such as the Suboxone Clinic. Thus, prior to issuing the Subpoena, the Government filed an “Application for an Order Authorizing Disclosure and Use of Substance Abuse Patient Records pursuant to 42 U.S.C. § 290dd-2(b)(2)(C) and 42 C.F.R. § 2.66” (“Application”). *See* Case No. 4:22-MC-00280 SPM, Doc. 4. On March 31, 2022, United States Magistrate Judge Shirley P. Mensah (the “Magistrate Judge”), in Case No. 4:22-MC-00280 SPM, issued an order (“Authorization Order”) authorizing the disclosure and use of records [REDACTED]

[REDACTED] (“Substance Abuse Patient Records”). *Id.*, Doc. 5.

receiving illegal kickbacks for referrals, in violation of 42 U.S.C. § 1320a-7b(b) and 18 U.S.C. § 2. Counts 36 through 43 charge Librach and Ali with executing a health care fraud scheme from in or about 2015 to in or about 2018, in violation of 18 U.S.C. §§ 1347 and 2. Count 44 charges Hydar with making materially false statements involving the Medicare program in 2018, in violation of 18 U.S.C. §§ 1035 and 2.

After receiving the Subpoena and a copy of the Authorization Order on May 27, 2022,² Librach's counsel requested an extension of the production date from June 10, 2022, to June 24, 2022. The Government agreed to the extension. On July 5, 2022, Librach's counsel informed the Government that Librach intended to file a motion to quash the Subpoena. In an email, the Government offered to confer with Librach's counsel regarding the basis for the motion to quash, but Librach's counsel did not respond until after filing the Motion.

On the same day—July 5, 2022—Librach filed the Motion currently before the Court. The Motion seeks two forms of relief. First, it asks this Court to amend or revoke the Authorization Order, which was issued by the Magistrate Judge who entered the Authorization Order after consideration of all the supporting materials filed contemporaneously therewith in a separate miscellaneous case number, Case No. 4:22-MC-00280 SPM.

Second, the Motion seeks to quash the Subpoena on the purported bases that: (1) the patient records are not “reasonably related to any lawful purpose of the Department of Justice in connection with” this case, Motion ¶ 7; (2) four of the five patient records are not relevant because the patients are not insured by Medicare or Medicaid; (3) the production of the five patient records would be unduly burdensome and oppressive, requiring an “excessive amount of time and financial expense,” Motion ¶ 3; (4) the Government is not investigating an “extremely serious crime” sufficient to warrant disclosure of Substance Abuse Patient Records that contain confidential patient communications pursuant to 42 C.F.R. § 2.63(a)(2); (5) authorizing the disclosure of Substance Abuse Patient Records violates patient confidentiality and deters patients from seeking treatment for substance abuse disorders; and (6) the Government improperly used “informants” to

² Although the Authorization Order was entered *ex parte* and under seal, [REDACTED]
[REDACTED]. Authorization Order, Case No. 4:22-MC-00280 SPM, Doc. 5 ¶ 10.

gather and share information about patients and employees of the Suboxone Clinic prior to obtaining the Authorization Order, which was, in turn, granted in part because of that alleged wrongfully obtained evidence.

II. ARGUMENT

Because the Subpoena at issue is an administrative subpoena seeking Substance Abuse Patient Records from a Suboxone Clinic, two separate statutes and their respective regulations impact this Court’s consideration of the Motion: (1) 18 U.S.C. § 3486 of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and 45 C.F.R. § 164.512 (sometimes referred to as the “HIPAA Privacy Rule”); and (2) 42 U.S.C. § 290dd-2 and 42 C.F.R. § 2.1 *et seq.* (sometimes referred to as the “Part 2” regulations). Each is addressed in turn below.

A. The Subpoena Comports with 18 U.S.C. § 3486 and the HIPAA Privacy Rule

Under 18 U.S.C. § 3486 (“Section 3486”) of HIPAA:

In any investigation relating of . . . a Federal health care offense, . . . the Attorney General . . . may issue in writing and cause to be served a subpoena . . . requiring the production . . . of any records or other things relevant to the investigation; and . . . testimony by the custodian of the things required to be produced concerning the production and authenticity of those things.

18 U.S.C. § 3486(a)(1)(A)-(B).

In 2003, as authorized by HIPAA, the Secretary of the Department of Health and Human Services (“HHS”) promulgated “Standards for Privacy of Individually Identifiable Health Information,”³ which generally prohibit the disclosure of individually identifiable health

³ Prior to the issuance of the HIPAA Privacy Rule, the Eighth Circuit and other circuits had held that no general physician–patient privilege was recognized in federal criminal cases. *See, e.g., United States v. Bercier*, 848 F.2d 917, 920 (8th Cir. 1988); *Hancock v. Dodson*, 958 F.2d 1367, 1373 (6th Cir. 1992); *United States v. Moore*, 970 F.2d 48, 50 (5th Cir. 1992); *but see Jaffee v. Redmond*, 518 U.S. 15 (1996) (recognizing a privilege for confidential communications between a patient and a psychotherapist). Therefore, Librach’s passing argument to quash the Subpoena based on a general physician-patient privilege fails. *See* Motion ¶¶ 2, 9.

information or protected health information (“PHI”) without the consent of the individual. 45 C.F.R. § 164.512. However, the HIPAA Privacy Rule permits disclosure of PHI in specified circumstances, including but not limited to disclosures as required by law, disclosures for “health oversight,” disclosure to law enforcement agencies, and disclosure for use in judicial proceedings. 45 C.F.R. § 164.512. For each permitted disclosure of PHI, the HIPAA Privacy Rule specifies the requirements for the disclosure.

Most relevant to this Motion is 45 C.F.R. § 164.512(d), which permits the disclosure of PHI to agencies performing health oversight activities. Under this section, a covered entity⁴ may disclose PHI to a health oversight agency for oversight activities authorized by law, including

audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of (i) the health care system; (ii) Government benefit programs for which health information is relevant to beneficiary eligibility

DOJ acts as a health oversight agency when subpoenas are issued as part of a federal criminal investigation of federal health care fraud offenses.⁵

1. Standards for Enforcing 18 U.S.C. § 3486 Administrative Subpoenas

The standards for enforcing administrative subpoenas have been clearly stated in numerous cases decided before and after the enactment of 18 U.S.C. § 3486. In 2008, the Eighth Circuit

⁴ A “covered entity” is a health care provider that transmits electronic information, a health plan, and a health care clearinghouse and their business associates. 45 C.F.R. § 160.103. DOJ is not a covered entity.

⁵ When acting as a law enforcement agency, DOJ may obtain PHI with a court order, grand jury subpoena, warrant or subpoena issued by a judicial officer, or an administrative subpoena. 45 C.F.R. 164.512(f)(1)(ii)(A)-(C). However, when acting as a law enforcement agency, DOJ’s request for PHI must be “specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought and De-identifiable information could not reasonably be used.” 45 C.F.R. 164.512(f)(1)(ii)(C). Importantly, the “De-identifiable information” requirement is not applicable to administrative subpoenas issued by DOJ when carrying out health oversight activities.

stated that it was well established that administrative subpoenas are “properly enforced if (1) issued pursuant to lawful authority, (2) for a lawful purpose, (3) requesting information relevant to the lawful purpose, and (4) the information sought is not unreasonable.” *Fresenius Medical Care v. United States*, 526 F.3d 372, 375 (8th Cir. 2008); *see also United States v. McDonnell Douglas Corp.*, 751 F.2d 220, 226 (8th Cir. 1984), *citing Oklahoma Press Pub. Co. v. Walling*, 327 U.S. 186, 215-16 (1946) (articulating four-part test for enforcement of administrative subpoenas). Applying these standards, the Eighth Circuit denied Fresenius’ motion to quash a Section 3486 subpoena issued by DOJ in a health care fraud investigation. *Fresenius*, 526 F.3d at 375; *see also United States v. Whispering Oaks Residential Care Facility, LLC*, 673 F.3d 813, 817 (8th Cir. 2012) (denying motion to quash Section 3486 subpoenas).

Moreover, if an agency has satisfied the requirements for an administrative subpoena, the burden shifts to the party seeking to quash the subpoena to demonstrate the subpoena is defective or to show that judicial enforcement “would amount to an abuse of the court’s process.” *Whispering Oaks*, 673 F.3d at 871, *citing E.E.O.C. v. Peat, Marwick, Mitchell & Co.*, 775 F.2d 928, 931 (8th Cir.1985).

2. DOJ Lawfully Issued the Subpoena

The Subpoena was authorized by 18 U.S.C. § 3486, which was enacted “to facilitate enforcement of federal statutes relating to healthcare fraud and abuse and thereby to promote the availability and affordability of health insurance in the United States.” *In re Subpoena Duces Tecum*, 228 F.3d 341, 346 n. 1 (4th Cir. 2000) (citation and internal quotation marks omitted); *see also Matter of Administrative Subpoena Served Upon Missouri Baptist Medical Ctr.*, 2022 WL 1802809, at *3 (E.D. Mo. June 2, 2022) (denying motion to quash Section 3486 subpoena).

Section 3486 expressly authorizes the Attorney General or his or her designee, in any investigation of a federal health care offense, to issue in writing and cause to be served a subpoena requiring the production of any records or other things relevant to the investigation. *Whispering Oaks*, 673 F.3d at 817, citing *Fresenius*, 526 F.3d at 375. In the instant case, the undersigned Government counsel have been delegated the authority to issue Section 3486 subpoenas.

Moreover, Section 3486 subpoenas may be utilized after indictment to investigate additional charges or to discover evidence related to the charges in the original indictment. *United States v. Wachter*, 2006 WL 2460790, at *6-7 (E.D. Mo. Aug. 23, 2006) (the government may use a Section 3486 administrative subpoena, issued to third parties, to continue to investigate pending charges); *United States v. Rakhit*, 2020 WL 5530056, at *23 (N.D. Ohio Sept. 15, 2020) (observing that Section 3486 health care administrative subpoena may be used post indictment but may not be issued to a defendant charged in the indictment); *United States v. Lazar*, 2006 WL 3761803, at *8-10 (W.D. Tenn. Dec. 20, 2006) (Section 3486 authorizes the government to obtain evidence related to charges in a pending indictment); see also *United States v. Daniels*, 2000 WL 764951, at *4-5 (D. Kan. May 22, 2000) (denying motion to quash Section 3486 subpoenas issued post indictment).

3. The Subpoena Was Issued for a Lawful Purpose

The second requirement for the enforcement of a Section 3486 subpoena is that the subpoena be issued for a lawful purpose. Those seeking to quash a Section 3486 subpoena bear a “heavy burden to disprove the existence of a valid purpose for an administrative subpoena.” *Whispering Oaks*, 673 F.3d at 817 (citations omitted).

Nonetheless, Librach contends that the patient records are not “reasonably related to any lawful purpose of the Department of Justice in connection with the above styled case.” Motion

¶ 7. Librach mistakenly suggests that Section 3486 subpoenas may only be used to obtain information about a pending case. However, neither the language of Section 3486 nor cases interpreting Section 3486 contain such a restriction. To the contrary, courts have held that Section 3486 subpoenas have a lawful purpose when issued as part of a criminal health care fraud investigation related to the provision and reimbursement of health care benefits, items, and services. *See e.g., In re Subpoena Duces Tecum*, 228 F.3d 341, 346 n.1 (4th Cir. 2000) (Section 3486 was enacted “to facilitate enforcement of federal statutes relating to healthcare fraud and abuse and thereby to promote the availability and affordability of health insurance in the United States.”).

Here, DOJ issued the Subpoena as part of its continuing investigation of the federal health care offenses⁶ alleged in the superseding indictment *and* its investigation of federal health care offenses involving *other* individuals and entities. Such individuals and entities include, for example, the clinical laboratories and affiliated individuals who paid Librach and his co-conspirators illegal kickbacks and who thereafter—as part of an overarching scheme—submitted fraudulent reimbursement claims to *both* public and private health insurers for tests on the specimens received in exchange for the kickbacks. Merely because some of the patients of the Suboxone Clinic were privately insured (such as some of the individuals whose records are sought in the Subpoena) does not mean that those individuals have no relevance to the healthcare fraud and kickback schemes at issue in this matter. Thus, DOJ unquestionably issued the Subpoena for

⁶ Under 18 U.S.C. § 24, a “Federal health care offense” is defined as a violation of or a conspiracy to violate specific federal statutes, including 18 U.S.C. §§ 1347 and 1035, and violations of other specified federal statutes if the violation relates to a health care benefit program, which is defined as “any public or *private* plan or contract . . . under which any medical benefit, item, or service is offered to any individual . . .” (emphasis added).

the lawful purpose of investigating alleged federal health care offenses affecting public and private health care insurers.

4. The Subpoena Seeks Relevant Information

As stated above, the third requirement for a Section 3486 subpoena is that the requested information be relevant to a lawful investigation. Librach asserts that four of the five patient records sought by the Subpoena are irrelevant to the pending case because the four patients are not Medicare and Medicaid patients. However, as discussed above, Librach's interpretation of the "relevance" requirement is too narrow and is inconsistent with numerous cases describing the breadth of the relevance requirement for administrative subpoenas.

In *Whispering Oaks*, the Eighth Circuit recognized that relevance, when considering a Section 3486 administrative subpoena, should be broadly defined. The Court stated: "The Government, with its subpoena power, 'does not depend on a case or controversy for power to get evidence but can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not.'" *Whispering Oaks*, 673 F.3d at 818, *quoting United States v. Morton Salt Co.*, 338 U.S. 632, 642–43 (1950); *see also Equal Employment Opportunity Commission v. Elrod*, 674 F.2d 601, 613 (7th Cir. 1982) (holding an administrative subpoena will survive a challenge that the material is not relevant if the material "touches" a matter under investigation).

Other courts have also recognized that Section 3486 grants the government "broad subpoena power." *Doe v. United States*, 253 F.3d 256, 265–66 (6th Cir. 2001) (noting the "broad subpoena power that the statute gives to the Attorney General and her designees"); *United States v. Lazar*, 2006 WL 3761803, at *10 (W.D. Tenn. Dec.20, 2006) (noting that "§ 3486 entrusts the government with broad subpoena powers").

As the Sixth Circuit stated in *Doe*, “it appears clear, both from the language of the statute and from Congress’s intent in enacting HIPAA, that the DOJ’s subpoena power in investigating federal health care offenses is meant to be broad.” 253 F.3d at 267. “Section 3486 authorizes the Attorney General or her designee to subpoena any records ‘*which may be relevant*’ to an authorized investigation, thus illustrating the substantial scope of the subpoena power Congress intended to give to the Attorney General.” *Id.* (citations omitted and emphasis in original). “Aside from the statutory language, other evidence of Congress’s intent to grant the Attorney General a broad subpoena power can be found in HIPAA’s legislative history. One of the main legislative purposes of HIPAA was to prevent health care fraud and abuse.” *Id.* (citations to legislative history omitted).

Courts have also held that an agency’s determination of relevance should be given considerable deference. *Doe*, 253 F.3d at 266. The standard for determining the relevance of a subpoena’s requests is not particularly burdensome, and indeed, a subpoena “should be enforced when the evidence sought by the subpoena is not plainly incompetent or irrelevant to any lawful purpose of the agency in the discharge of its duties.” *Whispering Oaks*, 673 F.3d at 817, *quoting Doe*, 253 F.3d at 266.

“[T]he language of § 3486 indicates that the question of an administrative subpoena’s relevance is not a question of evidentiary relevance.” *Whispering Oaks*, 673 F.3d at 818, *citing Doe*, 253 F.3d at 266. The question simply is whether the documents requested pursuant to the subpoena are relevant to the health care fraud investigation being undertaken. *Id.* In other words, subpoenas are not limited to seeking documents that would be admissible in judicial or administrative proceedings.

The Subpoena at issue here requests patient records that are clearly relevant to the

Government's investigation of the alleged health care fraud offenses involving Librach, Hydar, and employees and patients of the Suboxone Clinic. An examination of the records will likely reveal the identities of the labs which received specimens from the Suboxone Clinic, the type and frequency of services provided to privately-insured patients compared to Medicare and Medicaid patients, the similarity or difference between the services Librach and his employees provided at the Suboxone Clinic and the services provided at the American Pain Institute and later at the Institute for Pain Management—which Librach owned and for which he was at times the medical director. The patient records may also identify the person(s) who actually provided medical services, signed prescriptions and urine drug requisitions, entered information into the patient records, billed for services, gathered and submitted additional information to insurers when a claim was denied or questioned, received the transmittal notices and payments, and reconciled the payments with the claims submitted. Most of this information can only be found in the patient records created and maintained by the Suboxone Clinic.

The patient records may also assist the Government in identifying specific instances or a recurring pattern where Librach's employees, with his knowledge and concurrence, billed inappropriately or fraudulently. Additionally, these documents may contain information that is relevant to Librach's and his co-conspirators' knowledge of proper coding and billing procedures, thereby shedding light on their intent related to the alleged medically unnecessary services and false billing. Lastly, the records may include statements by Librach, his co-conspirators, or his representatives made on his behalf.

5. The Subpoena is Reasonable and Compliance is Not Unduly Burdensome or Oppressive

Librach next argues that the Subpoena is unreasonable and unduly burdensome and oppressive because the Subpoena requests *five* patient files dated from 2013 to the present—about

9.5 years. This argument borders on the frivolous. Undoubtedly, Librach and the Suboxone Clinic have in the past received requests for patient records from health care insurers, patients, and the patients' doctors and lawyers. Thus, the Suboxone Clinic has in place or can readily put in place a process for producing records relating to *five* patients. *See In re Subpoena Duces Tecum*, 228 F.3d 341, 349-51 (4th Cir. 2000) (finding a Section 3486 subpoena request for thousands of patient files and controlled substance records reasonably related to investigation of doctor).

Importantly, the Suboxone Clinic did not indicate prior to filing the Motion⁷ that compliance with the Subpoenas would be unreasonably burdensome and oppressive. Nor in the Motion does the Suboxone Clinic indicate why or in what way compliance with the Subpoena will be an undue burden. Given the specificity and limited number of documents sought, compliance with the Subpoena by the Suboxone Clinic will not be unreasonably burdensome or oppressive. *See Whispering Oaks*, 673 F.3d at 819 (rejecting overbreadth objection to Section 3486 subpoena when company offered no reason why enforcement and compliance with subpoenas would be overly burdensome); *Doe*, 253 F.3d at 268–69 (enforcing administrative subpoena where individual made only “general and conclusory statements” as to undue burden of the subpoena).

B. The Court’s Order Properly Authorizes Disclosure of Substance Abuse Patient Records Pursuant to the PHSA and Part 2 Regulations

Librach’s Motion asks this Court to set aside or amend the Authorization Order—which was entered in a separate case by the Magistrate Judge who had before her all the briefing and evidence in support of the Application. *See generally* Case No. 4:22-MC-00280 SPM. As discussed below, Librach provides no valid reasons for this Court to alter or revoke the

⁷ Upon being informed on July 5, 2022, that Librach intended to file a motion to quash the Subpoena, Government counsel sent an email on July 5, 2022, to defense counsel inviting him to contact Government counsel to discuss the Subpoena. Defense counsel did not respond to the email until after the Motion was filed.

Authorization Order entered by the Magistrate Judge. Because the Authorization Order was properly granted, it permits disclosure of the Substance Abuse Patient Records sought by the Subpoena.

1. Standard for Granting the Authorization Order

The disclosure of records relating to substance abuse treatment at federally-assisted facilities⁸ is governed by 42 U.S.C. § 290dd-2, a provision of the PHSA. Under that provision, “[r]ecords of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any [federally assisted] program . . . relating to substance use disorder . . . treatment,” *i.e.* Substance Abuse Patient Records, are confidential unless authorized by certain statutory exceptions. 42 U.S.C. § 290dd-2(a). The purpose of this rule and its implementing regulations is “to protect patients, not physicians, from criminal prosecution while they are seeking treatment for addiction.” *United States v. Pompy*, 2021 WL 978797, at *5 (E.D. Mich. Mar. 16, 2021). The regulations are expressly “intended to ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment.” 42 C.F.R. 2.2(b)(2).

As pertinent here, one such exception applies when a court grants an order authorizing disclosure of the subject patient records upon an “application showing good cause therefor, including the need to avert a substantial risk of death or serious bodily harm.” 42 U.S.C. § 290dd-2(b)(2)(C). The statute instructs courts assessing good cause to “weigh the public interest and the

⁸ The Suboxone Clinic was federally-assisted because, among other things, Librach was a participating provider in the Medicare and Medicaid programs during the relevant timeframe, and he submitted claims for payment to, and received payments from, those programs for his services at the Suboxone Clinic. 42 C.F.R. § 2.12(b)(2)(i).

need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.” *Id.* It further instructs courts granting disclosure of Substance Abuse Patient Records to “impose appropriate safeguards against unauthorized disclosure.” *Id.*

Under 42 U.S.C. § 290dd-2(g), the Secretary of the United States Department of Health and Human Services (the “Secretary”) has the authority to promulgate regulations, *i.e.* the Part 2 regulations, to further carry out the purpose of the statute, including to establish “procedures and criteria for the issuance and scope of orders” contemplated in subsection (2)(b)(C). One such regulation promulgated by the Secretary sets forth procedures and criteria relevant here, *i.e.* those authorizing disclosure and use of Substance Abuse Patient Records to investigate or prosecute a federally-assisted substance abuse treatment program or its employees or agents. 42 C.F.R. § 2.66.

Under 42 C.F.R. § 2.66, an order authorizing the disclosure of Substance Abuse Patient Records may be applied for in connection with, among other things, the criminal investigation of a federally-assisted substance abuse treatment program or its employees or agents. 42 C.F.R. § 2.66(a)(1). “The application may be filed separately or as a part of a pending civil or criminal action against” the target of the investigation. 42 C.F.R. § 2.66(a)(2). The regulations instruct that, to find the requisite “good cause” exists to enter an order in such a matter, the Court must simply find that: (1) “[o]ther ways of obtaining the information are not available or would not be effective;” and (2) “[t]he public interest and need for disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.” 42 C.F.R. §§ 2.64(d), 2.66(c). If the sought-after records include disclosure of confidential communications made by a patient, the court must also find that either (1) disclosure is necessary to protect against serious bodily injury or threat to life, or (2) disclosure is necessary in connection with the investigation of

an extremely serious crime, such as one that directly threatens bodily injury or loss of life.⁹ 42 C.F.R. § 2.63. In the Court’s discretion, the order may be granted without notice to the program or its patients. 42 C.F.R. § 2.66(b).

Librach challenges the Authorization Order on three main bases. First, he contends that no extremely serious crime is being investigated to justify disclosure of confidential communications made by a patient pursuant to 42 C.F.R. § 2.63. Second, Librach argues that the Authorization Order jeopardizes patient confidentiality and threatens to deter patients from seeking treatment for substance abuse. Third, Librach asserts that the Government improperly used informants to seek and obtain protected information about patients prior to asking for entry of the Authorization Order. None of Librach’s arguments have merit.

2. An Extremely Serious Crime Is Being Investigated

In arguing that the Government is not investigating any extremely serious crime to justify disclosure of confidential patient communications,¹⁰ Librach makes much of paragraph 5 of the Authorization Order. In paragraph 5, [REDACTED]

[REDACTED]

⁹ Although not currently applicable in this matter, this requirement is also satisfied when “[t]he disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.” 42 C.F.R. § 2.63.

¹⁰ Librach’s arguments do not apply to all of the records sought in the Subpoena, as 42 C.F.R. § 2.63 applies only to “confidential communications” made by a patient, not patient records in general. *In re K.S.*, 2021 WL 4817849, at *3 (Vt. Oct. 15, 2021) (concluding that a urinalysis test result is “plainly not a confidential communication” afforded the protections of 42 C.F.R. 2.63).

Authorization Order, Case No. 4:22-MC-00280 SPM, Doc. 5 ¶ 5 (emphasis added). From there—

██¹¹—Librach mistakenly argues that the misuse of a signature stamp is not an “extremely serious crime” sufficient to justify disclosure of confidential communications made by a patient pursuant to 42 C.F.R. § 2.63(a)(2). Motion ¶¶ 15-16.

Librach misses the point. In paragraph 5 of the Authorization Order,

MC-00280 SPM, Doc. 5 ¶ 3(c). Disclosure of the records sought in the Subpoena is necessary in connection with the investigation of extremely serious crimes other than the misappropriation of a signature stamp, including potential crimes that could put patients at risk of serious bodily injury or threat to life.

Librach incorrectly suggests that, to obtain confidential communications, the Government must be investigating one of the exemplary serious crimes specified in 42 C.F.R. § 2.63(a)(2), such

¹¹ The Application, Authorization Order, and attendant documents were filed under seal and *ex parte* because they reflect covert details of the Government’s ongoing investigation. Additionally, filing the Application under seal and *ex parte* protects witnesses mentioned in the Application from intimidation and harassment—particularly in light of Hydar’s multiple recent attempts to make contact with potential witnesses. Although the witnesses are not identified by name in the Application, their identities could likely be discerned from context. A motion to unseal the Authorization Order is currently pending.

as armed robbery, child abuse or neglect, or kidnapping. *See* Motion ¶ 16. However, the regulation is clear that the specifically enumerated crimes are merely examples, and that any crime “which directly threatens loss of life or serious bodily injury” will suffice. 42 C.F.R. § 2.63(a)(2). For this reason, in *Ohio State Dental Board v. Healthcare Venture Partners, LLC*, the court allowed a state dental board to access an oral surgeon’s confidential communications pursuant to 42 C.F.R. § 2.63 based upon allegations that the surgeon was alcohol-impaired while at work. 14 N.E.3d 470, 476-77 (Oh. App. 2014). The court explained that “[t]he interest in protecting the public from an impaired oral surgeon with a substance abuse problem [was] intuitively obvious,” as there was “a danger of serious harm to the public due to [the surgeon’s] inability to practice under accepted professional standards due to his alcohol dependency.” *Id.* at 477. Even though the surgeon’s license was under suspension, the court remained concerned about “the risk of the suspension being lifted or his return to practice” and found that the situation presented such a profound “threat to public safety” that it “greatly outweigh[ed]” the potential harm to the surgeon (*i.e.* the patient in that case). *Id.*

The conduct being investigated here involves, among other things, prescribing decisions regarding highly dangerous controlled substances being made by unqualified personnel. This conduct, which fails to adhere to “accepted professional standards,” *Ohio State Dental Board*, at 477, is made even more concerning by virtue of the fact that the Suboxone Clinic serves a particularly vulnerable population of patients, putting them at even higher risk of overdose and death. Indeed, the Government is concerned that this conduct and these risks are ongoing. Contrary to Librach’s insinuations, merely because the crimes being investigated are not specifically mentioned in 42 C.F.R. § 2.63 does not mean that the crimes are not extremely serious and warrant disclosure of confidential communications.

Nor is Librach correct in his apparent assumption that the Government seeks to charge one or more defendants with a crime merely by virtue of their use of a signature stamp. *See* Motion ¶ 19 (setting forth purported reasons that using a signature stamp may be proper). The subject Substance Abuse Patient Records will assist the Government in investigating other crimes, including alleged violations of 18 U.S.C. § 371 (conspiracy), 18 U.S.C. § 1035 (false statements related to health care matters), 18 U.S.C. § 1347 (healthcare fraud), 42 U.S.C. § 1320a-7b(b)(1)(B) (receiving illegal kickbacks for referrals), and 21 U.S.C. § 841(a)(1) (invalid prescribing of controlled substances). The misappropriation of Librach’s signature stamp—far from comprising the sole topic of the investigation—comprises one exemplary deceptive act through which Hydar furthered her goal of obtaining as many urine samples as possible to refer to laboratories in exchange for kickbacks.

3. Because Patient Confidentiality Will Be Protected, Patients Will Not Be Deterred from Seeking Treatment

Librach’s second argument to overturn the Authorization Order is that “[a]llowing the Government to gain access to Substance Abuse Patient Records and interview such Suboxone program participants would eliminate the confidentiality of [the] substance abuse program and risk deterring those very patients from seeking further help.” Motion ¶ e.¹²

This argument ignores the language of the Authorization Order, [REDACTED]

[REDACTED]

[REDACTED]. Authorization Order, Case No. 4:22-MC-00280 SPM, Doc. 5 ¶¶ 6-10. [REDACTED]

[REDACTED]

[REDACTED]. *Id.* ¶ 6. [REDACTED]

¹² On page 5 of the Motion, the paragraph headings change from sequential numbers to sequential letters.

[REDACTED].¹³ *Id.*

¶ 7. [REDACTED]

[REDACTED]. *Id.* ¶ 8. [REDACTED]

Id. ¶ 9.

Because adequate safeguards are in place, patient confidentiality will remain protected and disclosure of the Substance Abuse Patient Records will not deter patients from seeking legitimate substance abuse treatment. *See United States v. Kesari*, 556 F. Supp. 3d 571, 578-79 585 (S.D. W. Va. 2021) (magistrate judge properly found that the public interest and need for disclosure outweighed potential injury to patients where the Government argued that physician’s Suboxone prescribing practices “potentially endanger[ed] patients . . . in that patients [were] receiving dangerous drugs without necessary oversight”); *Pompy*, 2021 WL 978797, at *5 (finding “the purpose of the regulation—to protect people who are seeking treatment for their drug addiction—[was] fulfilled” where the information obtained pursuant to a Part 2 authorization order could not be used to investigate or prosecute a patient legitimately seeking treatment).

4. The Government Did Not Use “Informants” to Obtain Part 2 Information Prior to Entry of the Authorization Order

Finally, “upon information and belief,” Librach accuses the Government of improperly using “informants” to obtain protected patient information prior to seeking entry of the Authorization Order. Motion ¶¶ h-s. Librach alleges that the Application was filed “after the

¹³ For this reason, Librach’s concerns about authorizing disclosure of un-redacted documents (*see* Motion ¶ 6) are unfounded. Un-redacted documents are critical to the Government’s ability to understand the medical records and to corroborate what certain witnesses have stated with respect to specific patients.

fact,” *id.* ¶ m, and that the Government included within its Application inappropriately obtained information to secure the Authorization Order. *Id.* ¶ s. Librach’s unsupported allegations have no basis in fact.

Under the Part 2 regulations, an “informant” is defined as an individual:

- (1) Who is a patient or employee of a part 2 program or who becomes a patient or employee of a part 2 program at the request of a law enforcement agency or official;
and
- (2) Who at the request of a law enforcement agency or official observes one or more patients or employees of the part 2 program for the purpose of reporting the information obtained to the law enforcement agency or official.

42 C.F.R. § 2.11 (emphasis added). The Government did speak with former patients and employees of the Suboxone Clinic about their experiences prior to seeking entry of the Authorization Order. In fact, it is difficult to fathom how the Government would have been able to make the requisite good cause showing in support of disclosure *without* taking the noncontroversial step of interviewing witnesses. However, despite his accusations, Librach points to no evidence that the Government requested any *current* employees or patients of the Suboxone Clinic to make *new* observations of the Suboxone Clinic, much less to report them back to the Government. Librach has no such evidence because these actions simply never happened; the Government did not use informants.

III. CONCLUSION

In conclusion, the Government has demonstrated herein that no federally recognized physician-patient privilege, federal statute, or federal regulation bars disclosure of the records sought by the Subpoena; DOJ obtained and strictly complied with the Court’s March 31, 2022, Authorization Order permitting DOJ to receive the patient records; DOJ complied with the requirements for the issuance of the Subpoena under 18 U.S.C. § 3486; and compliance with the Subpoena will not be unduly burdensome or oppressive. Therefore, the Government respectfully

urges the Court to deny the Motion to quash the Subpoena and to deny the request for revocation or amendment of the March 31, 2022, Authorization Order.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2022, the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system upon all counsel of record. An unredacted version of this document was also served upon counsel for Stanley Librach via email.

/s/ Amy E. Sestric

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